Exhibit 4

R5

The ASAM Principles of Addiction Medicine

SIXTH EDITION

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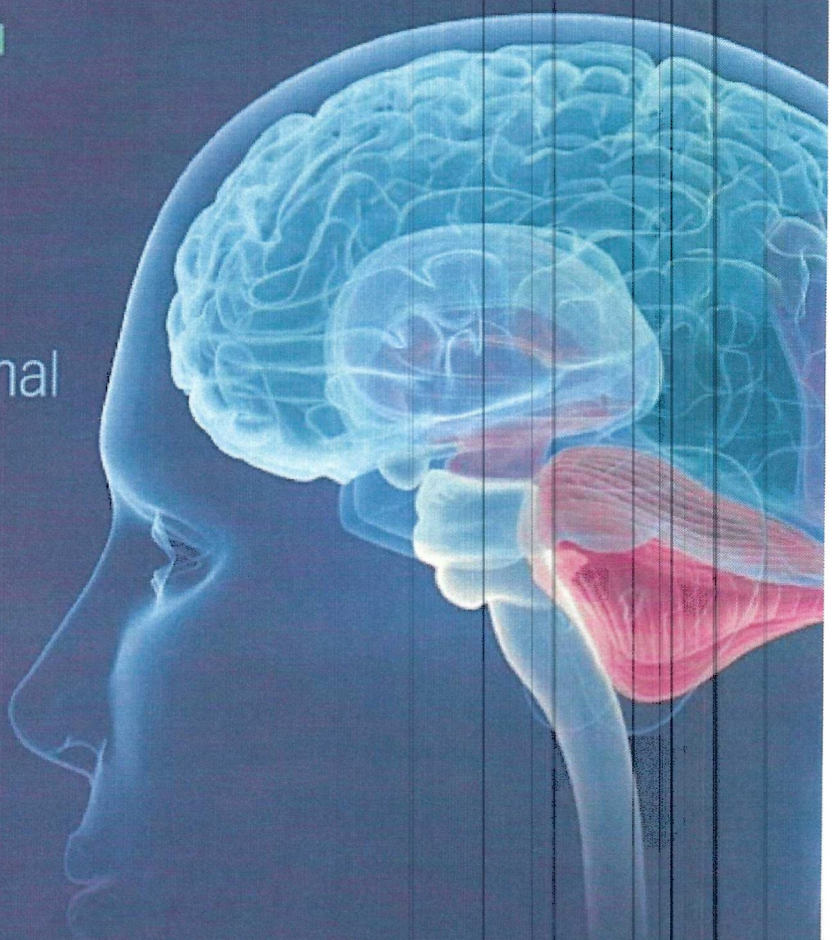

Wolters Kluwer

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Under federal law, every prescription order must include at least the following information (47):

Name and address of the patient
Name, address, and DEA registration number of the physician
Signature of the physician
Name and quantity of the drug prescribed
Directions for use
Refill information

Many states impose additional requirements, which the physician can determine by consulting the medical licensing board in his or her state (9). In addition, there are special federal requirements for drugs in different schedules of the federal CSA, particularly those in Schedule II (see the sidebar to this chapter).

Patients who are seeking controlled substances for nonmedical use are constantly on the lookout for blank prescription forms and often use the names of physicians who recently retired, left the state, or died. Therefore, storing blank prescription order forms in a safe place (eg, "double-locked," behind a locked door and in a locked cabinet)—as opposed to leaving the pads in examining rooms—is a sound practice. All states now have the capacity for electronic prescribing, which mostly obviates the risks of theft and forgery of controlled substance prescriptions.

Note: The physician should immediately report the theft or loss of blank prescription forms to the nearest field office of the federal DEA and to the State Board of Medicine or Pharmacy.

Maintaining Adequate Medical Records

In the event of a legal, regulatory, or civil (malpractice-related) challenge, detailed medical records documenting what was done and why are the foundations of the physician's defense. Every physician needs to know and understand the federal requirements for record keeping, as well as the laws and regulatory requirements of the state in which he or she practices. This is important because state laws and medical board rules may differ substantially from the federal requirements and from one state to another. The Board of Medical Licensure or the Board of Pharmacy (or their equivalent) in each state can provide information about the relevant requirements. At a minimum, patient records should contain the following information (25,53):

1. *Patient history and physical examination*: The patient record must include a history of all controlled medications used to treat the patient, any history of illicit substances, and any patient allergies. Regimens tried and failed also should be documented. Medical records obtained from providers who have treated the patient in the past should be included. The medical record also must include information about the patient's personal and family history of alcohol, tobacco, and other drug use, as well any personal history of major depression or other psychiatric disorder.
2. *Treatment plan*: The treatment plan and goals should be documented in the record so that there is evidence of clear-cut, individualized objectives to guide the choice of therapy. If the patient improves after a brief trial, that should be documented in the record, as should regimens tried and failed.
3. *Consultation reports*: Whenever the best clinical course is not clear or the patient's response is not as expected, consultation with another physician should be obtained. Generally, the results of the consultation should be discussed with the consulting physician and a written consultation report added to the patient's medical record.
4. *Prescription orders*: The patient record must include all prescription orders, whether written or telephoned. Written instructions for the use of all medications should be given to the patient and documented in the record. The prescription order itself should specify both the milligram dose and the volume of medication to be taken. Confusion related to ambiguous orders can lead to tragic outcomes, especially early in treatment. The physician should clearly specify the dose and formulation and how often the medication should be used.
5. *Informed consent or treatment agreement*: As noted earlier, a written informed consent and a treatment agreement signed by both patient and physician can be helpful in establishing a set of "ground rules" and appropriate expectations (67).
6. *Monitoring visits*: Medication monitoring visits are billable and can be performed by a nurse. They should be carefully documented in the medical record, in the same manner as a visit with the physician. A long-term controlled drug prescription flow sheet provides an efficient format for this documentation.
7. *Treatment progress/outcomes*: The patient's record should clearly reflect the decision-making process that led to any given medical outcome.

Good records demonstrate that a service was provided to the patient and that the service was both safe and medically necessary. Even if the outcome is less than optimal, thorough records protect the physician as well as the patient (25,68).

CONCLUSIONS

Like all clinical tools, medications with the potential for nonmedical use and addiction must be considered in terms of potential risks and benefits. Such medications can be effective in managing a number of challenging clinical syndromes but also are the source of serious morbidity and mortality if misused. It is the premise of this chapter that judicious use of these medications, with attention to proper assessment, collaborative informed consent and treatment planning, adequate monitoring, and intervention as needed can minimize the likelihood of nonmedical medication use and the attendant risks.

The "universal precautions" approach to decision-making regarding the prescribing of controlled medications and subsequent patient monitoring is an excellent way to systematically ensure that prescribing is for a legitimate medical purpose, occurred within the usual course of medical practice, and was done with concern for patient safety as the most important clinical consideration. Attention to these elements, along with careful record keeping, serves to lessen physicians' concerns about regulatory or legal scrutiny.